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10/006,027	12/07/2001	Richard James Riehle	10086 7696	
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)		
	10/006,027	RIEHLE ET AL.		
Office Action Summary	Examiner	Art Unit		
	William H. Beisner	1744		
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	86(a). In no event, however, may a reply be ting within the statutory minimum of thirty (30) day rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).		
Status				
1) Responsive to communication(s) filed on <u>26 May 2005 and 10 June 2005</u> . 2a) This action is FINAL . 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims				
4) ⊠ Claim(s) <u>1-38</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>1-38</u> is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or	vn from consideration.			
Application Papers				
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction of the original transfer of the correction of th	epted or b) objected to by the lideral or b) objected to by the lideral or by the li	e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priori application from the International Bureau * See the attached detailed Office action for a list of	have been received. have been received in Application ity documents have been received (PCT Rule 17.2(a)).	on No ed in this National Stage		
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/10/05.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:			

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DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 6/10/05 has been considered and made of record.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-21 and 34-38 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The additional step of contacting the composition with "at least one microorganism, or at least on enzyme located from the at least one microorganism, in an amount, and at a pH and temperature effective to dehalogenate residual quantities of organically bound halogen" is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claims 1-21 and 34-38 encompass a treatment process that includes treating a composition containing a wet strength polyamine-epihalohydrin resin comprising a solids content of at least 15 wt% with an enzymatic agent to inhibit, reduce or remove a CPD-forming species. The final amount of CPD-forming species remaining in the composition after the enzyme treatment is defined in terms of the "ACID TEST". That is, the treated composition

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when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD.

Review of the originally filed disclosure includes 38 Examples.

Example 1 is drawn solely to the manufacture of a wet strength polyamine-epihalohydrin composition with a solids content of 21.08% and includes CPD-forming species.

Example 2 is drawn to an enzymatic treatment of the composition of Example 1. The results of Example 2 do not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD". See table 1.

Example 3 is drawn to a biodehalogenation treatment of the treated composition of Example 2. It is noted that the treated composition of Example 2 is diluted prior to treatment with the microorganisms. As shown in Table 1 the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD".

Example 4 is drawn to a diluted composition of Example 1. The starting composition has a solids content less than 15 wt%.

Example 5 is drawn to a comparison of a paper product using the treated compositions of Examples 3 and 4.

Examples 6-19 are drawn to enzyme treatments of high solids (at least 15 wt%) wet strength polyamine-epihalohydrin compositions. While a high solids composition was treated with the enzyme composition, the tabulated data does not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD". See table 3.

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Example 20 is drawn to a combined enzyme-biodehalogenation treatment method of a diluted (less than 15 wt%) starting composition. While the "ACID TEST" establishes that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD", see table 4, the starting composition did not include a solids composition of at least 15 wt %.

Example 21 is similar to Example 20 but employs twice as much enzyme.

Example 22 is similar to Examples 20 and 21. This example employs a different starting composition but the solids content is still less than 15 wt%.

Example 23 is drawn to biodehalgenation of a starting composition of at least 15 wt%.

Example 24 is drawn to a sequential enzyme-biodehalogenation treatment process with a starting composition of at least 15 wt%. While the "ACID TEST" establishes that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD", see table 11, the treatment process employed both an enzyme treatment and biodehalogenation treatment.

Example 25 is drawn to a combined enzyme-biodehalogenation process of a starting composition of at least 15 wt%. While the "ACID TEST" establishes that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD", see table 12, the treatment process employed both an enzyme treatment and biodehalogenation treatment.

Examples 26-30 are limited to biodehalogenation of starting compositions of at least 15 wt% but do not involve an enzyme treatment as required of the instant claims.

Examples 31 and 32 are drawn to an enzyme treatment of a starting composition of at least 15 wt%. However, the resulting data does not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD". See tables 21 and 22.

Examples 33 and 34 are limited to biodehalogenation of starting compositions of at least 15 wt% but do not involve an enzyme treatment as required of the instant claims.

Example 35 is drawn to a combined enzyme-biodehalogenation process of a starting composition of at least 15 wt%. However, the resulting data does not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD". See tables 25 and 26.

Example 36 is limited to biodehalogenation of starting compositions of at least 15 wt% but do not involve an enzyme treatment as required of the instant claims.

Examples 37 and 38 are drawn to a combined enzyme-biodehalogenation process of a starting composition of at least 15 wt%. However, the resulting data does not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD". See tables 28 and 29.

In summary, only Examples 3, 24 and 25 are drawn to treatment methods that treat a starting composition with a solids content of at least 15 wt% wherein the treatment method includes the claimed enzyme treatment and establishes that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD". However, it is apparent to one of ordinary skill in the art that the biodehalogenation step is critical to the invention since each of these examples also included a biodehalogenation step as

part of the treatment process that resulted in a treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD". Note the examples that where drawn solely to an enzyme treatment of a starting composition of at least 15 wt% did not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 5. Claims 1-13, 19-21, 34-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Bull et al.(US 5,470,742).

With respect to claims 1 and 2, the reference of Bull et al. discloses a method of rendering a polyamine-epihalohydrin resin storage stable. The method discloses treating a composition containing a wet strength polyamine-epihalohydrin resin including a solids content of at least 15 wt% (See column 6, lines 43-48). The composition is treated with at least one enzymatic agent under conditions to at least one of inhibit, reduce and remove CPD-forming

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species (See column 7, line 40, to column 8, line 37). The final concentration of the CPD-forming species can be as low as 0.1 ppm (See column 11, lines 10-16).

With respect to claims 3 and 4, the reference discloses a temperature range of 10-50deg.C.(See column 10, lines 10-13).

With respect to claims 5 and 6, the reference discloses a time range of 6.5 to 15 hours (See column 11, lines 11-16).

With respect to claims 7-9, the reference discloses the use of pH ranges from 3-10 (See column 10, lines 14-24).

With respect to claims 10-13, the reference discloses a range of enzyme concentrations which appears to inherently meet the claim limitations of these claims (See column 10, lines 59-66).

With respect to claims 19-21, the reference discloses a number of exemplary epichlorohydrin resins (See column 5, line 57, to column 7, line 63).

With respect to claim 34, the disclosed reaction dehalogenates the halogens bound to the polymer backbone.

With respect to claims 35-38, the reference discloses making a paper product from the treated composition (See column 12, lines 31-43).

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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- 7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 9. Claims 1-12, 14-16, 18-25 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richle et al.(US 6,554,961 or US 2003/0205345) in view of Bull et al.(US 5,470,742).

The reference of Richle et al. discloses a process for rendering a polyamine-epihalohydrin resin storage stable, that includes treating a composition containing a wet strength polyamine-epihalohydrin resin, the composition comprising a solids content of at least 15 wt% (21%, see Example 75) and including CPD-forming species, with at least one enzymatic agent

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under conditions to at least one of inhibit, reduce and remove the CPD-forming species to obtain a gelation storage stable reduced CPD-forming resin so that the composition containing the reduced CPD-forming polyamine-epihalohydrin resin when stored for 24 hours at 50degC, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD (See Example 75 and Table 31).

Claim 1 differs by reciting that the concentration of the resin is at least 15% when contacted with the enzymatic agent.

The reference of Bull et al. discloses that when treating a composition that includes CPD-forming species it is known to treat a composition that includes a solids content of up to 50 wt% with an enzymatic agent (See column 6, lines 43-48).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum solids content based on considerations such as the source of the resin composition and the intended use of the resin composition while providing the benefits associated with the claimed treatment process as evidenced by the reference of Bull et al.

With respect to claim 2, see Table 31 that shows CPD ppms of 12.6 and 13.7.

With respect to claims 3 and 4, the enzyme treatment is performed at 40.0 deg. C (See column 89, lines 58-59).

With respect to claims 5 and 6, the enzyme treatment is performed for 6 hours (See column 89, line 62).

With respect to claims 7-9, the enzyme treatment is performed at a pH of 8 (See column 89, line 54).

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With respect to claims 10-12, the enzyme treatment is performed using an enzyme to resin ratio of 1:77.

With respect to claims 14-16 and 18, the reference discloses using the enzyme Alcalase (See column 89, line 55).

With respect to claims 19-21, the reference discloses the use of a number of resins (See column 16, lines 33-62).

With respect to the biological dehalogenation of claims 22-25, the reference discloses a subsequent dehalogenation step (See Example 75).

With respect to claim 34, the dehalogenation step meets this claim limitation (See column 17, lines 8-27).

With respect to claims 35 and 36, see Example 76 and 7 which are drawn to paper making steps with the produced product of Example 75.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/013,049. Although the conflicting claims are not identical, they are not patentably distinct from each other because while instant claim 1 recites "less than about 250ppm", claim 1 of application 10/013,049 recites the exact same claim limitation except uses the language "less than about 100 ppm". As a result, while the claims are of different scope, instant claim 1 is anticipated by claim 1 of application 10/013,049.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-25 and 34-36 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 10-15 of copending Application No. 10/396,155 in view of Bull et al.(US 5,470,742). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-7 and 10-15 of application 10/396,155 encompass a treatment process that is essentially the same as that of claims 1-25 and 34-36 of the instant application. The instant claims recite that the resin composition includes a solids content of at least 15%, while the claims of 10/396,155 are silent as to the solids content. The reference of Bull et al. discloses that when treating a composition that includes CPD-forming species it is known to treat a composition that includes a solids content of up to 50 wt% (See column 6, lines 43-48). In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum solids content based on

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considerations such as the source of the resin composition and the intended use of the resin composition while providing the benefits associated with the claimed treatment process as evidenced by the reference of Bull et al.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1-13 and 19-21 are rejected under the judicially created doctrine of obviousnesstype double patenting as being unpatentable over claims 7-13 and 15-20 of U.S. Patent No. 6,554,961 in view of Bull et al.(US 5,470,742). Claims 7-13 and 15-20 of U.S. Patent No. 6,554,961 encompass a method of treating a polyamine-epihalohydrin resin composition that includes CPD-forming species and is contacted with a microorganism or enzyme agent to dehalogenate residual quantities of organically bound halogen. The above claims differ by reciting that the starting composition includes a solids content of at least 15 wt% and includes a CPD-forming species final content of less than 250ppm. The reference of Bull et al. discloses that it is known in the art to treat a polyamine-epihalohydrin resin composition that includes CPD-forming species and is contacted with a microorganism or enzyme agent to dehalogenate residual quantities of organically bound halogen wherein the solids content can be up to 50 wt% (See column 6, lines 43-48). The reference also teaches that such a treatment results in a CPDforming species content in the range of 0.1ppm-500ppm (See column 11, lines 1-16). In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum solids content based on considerations such as the source of the resin composition and the intended use of the

resin composition while providing the benefits associated with the claimed treatment process as evidenced by the reference of Bull et al.

Response to Arguments

- 14. Applicant's arguments filed 5/26/05 have been fully considered but they are not persuasive.
- 15. With respect to the rejection of claims 1-21 and 34-38 under 35 USC 112, first paragraph, Applicants argue (See pages 8-10 of the response dated 5/26/05) that the rejection is improper because while the Examples do utilize biodehalogenation step as a means to reduce the amount of CPD present in the resin sample, the specification discloses additional treatments that may be used to reduce or remove CPD-forming species contained in the resins.

In response, the Examiner does not question that other means to reduce the amount of CPD present in the resin can be used. The issue at hand is that the instant claims require that a polyamine-epihalohydrin resin of at least 15% concentration is treated with an enzymatic agent such that it releases less than 250ppm dry basis CDP when subjected to the "ACID TEST". The instant specification stresses that when working with resin concentrations greater than 15% the results are unexpected when using enzymes (See page 9, lines 16-29 and page 40, line 27, to page 41, line 6, of the instant specification). Apparently in view of this unpredictability in the art, the instant specification includes 114 pages and 38 Examples. Of the 38 Examples, only a select few provided a polyamine-epihalohydrin resin of at least 15% concentration that is treated with an enzymatic agent such that it releases less than 250ppm dry basis CDP when subjected to

the "ACID TEST". All of these examples included the combined treatment of the resin with esterase active enzymes with biodehalogenation. These Examples establish that the combination of the esterase active enzyme agent and biodehalogenation are critical with respect to obtaining a product that is required of instant claim 1. While one of ordinary skill in the art may recognize that other CPD removing processes exist, in view of the unpredictability in the art, undue experimentation would be required for one of ordinary skill in the art to determine which if any of the other known treatment steps would provide the product required of claim 1.

- 16. With respect to the rejection of claims 1-12, 14-16, 18-25 and 34-36 over the reference of Richle et al. under 35 USC 102(e), Applicants comments (See pages 10-11 of the response dated 5/26/05) are persuasive to overcome the rejection of the claims under 35 USC 102. Note these claims as amended in the response dated 5/26/05 have been address in the combination of the references of Richle et al. and Bull et al.
- 17. With respect to the rejection of claims 1-13, 19-21 and 34-38 over the reference of Bull et al. under 35 USC 102, Applicants argue (See pages 11-13 of the response dated 5/26/05) that the rejection is improper because the products that result from the treatment provided by the reference of Bull et al. are not storage stable over time.

In response, Applicants' comments are not found to be persuasive because while the amount of CPD may increase over time the amount of CPD in the resin composition is still below the amount required of claim 1 and thus is considered to be "storage stable".

18. With respect to the provisional obviousness-type double patenting rejection of the claims over copending application 10/013,049, Applicants intend to file a terminal disclaimer once the other bases for objection and/or rejection of the pending claims have been removed.

19. With respect to the rejection of the claims under provisional obviousness-type double patenting rejection over the claims of 10/396,155 in view of Bull et al. and the obviousness-type double patenting rejection over the claims of US 6,554,961 in view of Bull et al., Applicants argue that the rejection is improper because one of ordinary skill in the art would not be motivated to combine the claims of the application /patent with the reference of Bull et al. because the reference of Bull et al. does not result in a treated composition that is storage stable.

In response, Applicants' comments are not found to be persuasive for the same reasons as set forth with respect to the rejection of claims over the reference of Bull et al. under 35 USC 102.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this

final action.

21. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to William H. Beisner whose telephone number is 571-272-1269.

The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Villiam H. Beisner

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Primary Examiner

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WHB